

**REMARKS**

Claims 1-6, 8-14 and 22-28 are pending. The Applicants appreciate that the Examiner has withdrawn one of the previous 35 U.S.C. § 112 rejection to Claims 1-6,8-14 and 22-27. Nonetheless, the Examiner has presents several rejections against the pending claims that are rebutted in the following order:

I. Rejections Under 35 U.S.C. § 103(a)

A. (Maintained) Claims 1, 3, 5-6, 8-9, 11, 13-14 and 22-27 are allegedly unpatentable over Ezaki et al., *Int. J. Sys. Bacteriol.* 39:224-229 (1989), in view of Hayward et al., *Mol. Microbiol.* 35:6-14 (2000); as evidenced by DeRisi et al., *Science* 278:680-686 (1997).

B. (Maintained) Claims 2, 4, 10, and 12 are allegedly unpatentable over Ezaki et al., *Int. J. Sys. Bacteriol.* 39:224-229 (1989), in view of Hayward et al., *Mol. Microbiol.* 35:6-14 (2000); as evidenced by DeRisi, as applied to Claims 1, 3, 5-6, 8-9, 11, 13-14 and 22-27 above, and in further view of United States Patent No. 6,228,575 To Gingeras.

C. (New) Claims 1-6, 8-14, and 22-27 are rejected under 35 U.S.C. 103(a) as allegedly unpatentable over Gingeras et al. (US Patent 6,228,575) in view of Hayward et al. (Mol. Microbiology, 2000, 35(1), 6-14) as evidenced by DeRisi (cited on 892 filed 11/19/2003).

D. (New) Claim 28 is rejected under 35 U.S.C. 103(a) as allegedly unpatentable over Gingeras et al. (US Patent 6,228,575) in view of Hayward et al. (Mol. Microbiology, 2000, 35(1), 6-14) as evidenced by DeRisi et al. and Legendre et al., (Numerical Ecology, Elsevier Science, Amsterdam, 1998).

E. (New) Claim 28 is rejected under 35 U.S.C. 103(a) as allegedly unpatentable over Ezaki et al. (Int.J. Sys. Bacteriol. 1989, vol. 39, pp. 224-229) in view of Hayward et al. (Mol. Microbiology, 2000, 35(1), 6-14) as evidenced by DeRisi et al. and Legendre et al.

II. Rejections Under 35 U.S.C. § 112 ¶ 1

A. Claims 22-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.<sup>1</sup>

**I. The Claims Are Not Obvious**

Obviousness is currently determined based upon an evaluation of the magnitude of the differences between the claimed embodiment and the asserted prior art:

In *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 86 S. Ct. 684, 15 L. Ed. 2d 545 (1966), the Court set out a framework for applying the statutory language of § 103 ... "Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained ...

*KSR v. Teleflex*, 127 S. Ct. 1727, 1734 (2007). Further, the *KSR* holding only cautioned against a strict application of the "teaching-suggestion-motivation test" such that an explicit teaching is not required to be found within the cited applications. Consequently, it is still required to: i) establish *some motivation* to combine the references either explicitly or implicitly, and ii) establish a *prima facie* case of obviousness, wherein the prior art reference (or references when combined) must teach or suggest all the claim limitations with a reasonable expectation of success. *In re Vaeck*, 947 F.2d 488, 20 USPQ.2d 1438 (Fed. Cir. 1991); and *MPEP* § 2142; Establishing A *Prima Facie* Case Of Obviousness. The Applicants submit that the Examiner has not made a *prima facie* case of obviousness.

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<sup>1</sup> The Examiner did not provide details regarding a potential rejection of Claims 23 and 25. The Applicants, therefore, have assumed the apparent inclusion of these claims in the present rejeciton to be a typographical error and have provided a response to Claims 22 and 24 as detailed in the Action.

*In re Keller*

The Applicants submit that the Examiner has misinterpreted *In re Keller*. *Office Action* pg 20 bridging pg 21. Unfortunately, *In re Keller* is continually being misused. The Applicants urge the Examiner to discuss this case with their Supervisor so your entire Art Unit can be provided with a better understanding of this *very narrow* holding.

*In re Keller* was decided upon an affidavit that discussed only one of three cited references:

As characterized by appellant, the Cywinski affidavit offered as objective evidence of non-obviousness "concerns itself mainly with the question of whether the Walsh et al. article suggest[sic] the use of ..." ... In the present case, we are not presented with a single prior art reference, but rather two combinations of three references. ... The affidavit does not indicate that Dr. Cywinski ... critically reviewed ... the two combinations of references.

*In re Keller*, 642 F.2d 413, 425-426, 208 USPQ 871 (CCPA 1981). Similarly, the citation relied upon by the Examiner within *In re Merck & Co.* involves a finding by the Federal Circuit that the presentation of a non-obviousness argument to only one cited reference (out a total of nine) is insufficient to overcome an obviousness rejection:

We also find untenable appellant's arguments that Petersen teaches away from appellants' invention. ... Thus, Petersen must be read, not in isolation, but for what it fairly teaches in combination with the prior art as a whole.

*In re Merck & Co.*, 800 F.2d 1091 1097, 231 USPQ 375 (Fed. Cir. 1986). This is not the case here. The Applicants' previous response provided an organized argument regarding each of the three references AND an integrated conclusion. Clearly, the Applicants' response to the Examiner's obviousness rejection does not fall within the scope of *In re Keller* or *In re Merck & Co.*

Consequently, the Applicants respectfully request that the Examiner admit that the previous response did discuss all the references and does not fall within *In re Keller*'s definition of 'attacking the references individually'.

**A. Claims 1, 3, 5-6, 8-9, 11, 13-14 and 22-27 Are Patentable Over Ezaki et al., Hayward et al., & DeRisi et al.**

**1. Ezaki et al. And Hayward Fail To Create A *Prima Facie* Case Of Obviousness**

**a. ‘Random Genomic DNA Sequences’ Are Not Taught**

The Examiner admits that:

Ezaki et al. does not teach providing amplified random genomic sequences to create a plurality of arrayed elements ...

*Office Action pg 15.* The Examiner then attempts to reassert Hayward et al. for allegedly teaching this missing claim element by stating:

Hayward et al. teach constructing a shotgun DNA microarray using random inserts from a genomic library ...

*Office Action pg. 15.* The Applicants disagree and herein incorporate by reference the arguments presented in the last response providing evidence from Hayward et al. that the arrayed genomic inserts are not random:

Such digestion was expected to capture long stretches of unique coding regions and avoid over-representation of flanking sequences or introns on the array.

*Hayward et al., pg 7 col 1 bridging col 2* [emphasis added]. Hayward et al. explicitly admits that *mung bean nuclease was used for at least two specific reasons and/or aims* (see above underlining). Such a strategy cannot be interpreted as “random”. The Examiner is respectfully requested to consider a common definition of the term “random”:

– adjective

1. proceeding, made, or occurring without definite aim, reason, or pattern:

*Dictionary.com* [emphasis added]. In rebuttal to the Applicant's last response, the Examiner argues that:

The combination of Ezaki and Hayward does teach random generation of amplified products as mung bean nuclease is not specific for a specific nucleic acid sequence thus the fragments that are generated by Hayward do not have any definite sequence and thus are random.

*Office Action* pg 22. The Examiner's logic is without any evidentiary basis and is contrary to what was known to one having ordinary skill in the art at the time Hayward et al. was published. At the outset, the Examiner alleges that Hayward's inserts are random because they do not have 'any definite sequence'. The Examiner has not provided any evidence acceptable to one having ordinary skill in the art to support that interpretation/definition of "random sequence". Further, and contrary to the Examiner's argument, Hayward et al. does, in fact, teach that mung bean nuclease has specificity:

Mung bean nuclease preferentially cuts malarial DNA in regions flanking coding regions (McCUTCHAN ET AL, 1984; VERNICK AND McCUTCHAN, 1998).

*Hayward et al., pg 7 col 1 bridging col 2* [emphasis added]. The Examiner is respectfully requested to consider the following excerpt from one the above citations in Hayward et al.:

Mung bean nuclease was found to cut the genomic DNA ... which had nearly the precision of a restriction nuclease ...

McCUTCHAN ET AL., "Mung bean nuclease cleaves *Plasmodium* genomic DNA at sites before and after genes" *Science* 1984 225(4662):625-628 (1984) [emphasis added; Abstract attached for the Examiner's convenience]. In fact, Hayward's other cited reference identifies further research

claims, Applicants have amended Claims 22 and 24 to recite "between 60 – 100,000 genomic sequences". These amendments are made not to acquiesce to the Examiner's argument but only to further the Applicants' business interests, better define one embodiment and expedite the prosecution of this application.

The Examiner is respectfully requested to withdraw the present rejection.

### **CONCLUSION**

In view of the above, Applicants respectfully request withdrawal of the rejections and passing the application to allowance.

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Peter G. Carroll  
Registration No. 32,837

MEDLEN & CARROLL, LLP  
101 Howard Street, Suite 350  
San Francisco, California 94105  
781/828.9870